FEB 1 4 2001

K003795

510(k) Summary of Safety and Effectiveness

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

This summary of 510(k) safety and effectiveness information is being submitted in accordance with 21CFR 807.92.

BioLucent Inc. intends to introduce into commercial distribution the Mammography Cushion. The equivalent predicate devices are the Foam Table Pad by St. John Companies and the Mammography Wedge by Contour Fabricators, Inc.

Simple products of this type include non-classified products (predicate devices described above) and Class I (e.g. CFR 892.1830) products. Therefore, BioLucent's device is a Class I medical device. The common name for BioLucent's product is foam pad, cushion.

The BioLucent Mammography Cushion is intended to provide padding for patient comfort during x-ray visualization of the breast.

The St John, the Contour Fabricators and the BioLucent foam products all provide for padding of the patient during x-ray visualization. In all 3 products, a sheet of foam is placed between the contact surface of the equipment and the patient, for comfort. The device labeling supports the use of these products in the discipline of radiology.

12-7-00

Steve Gex date
President
BioLucent, Inc.
27121 Aliso Creek Rd.
Suite 125
Aliso Viejo, CA 92656

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Steve Gex
President
BioLucent Inc.
27121 Aliso Creek Road
Suite 125
ALISO VIEJO CA 92656

Re: K003795
Biolucent Mammography Cushion
Dated: December 7, 2000
Received: December 8, 2000
Regulatory Class: II
21 CFR §892.1710/Procode: 90 IZH

Dear Mr. Gex:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known):

Device Name: Mammography Cushion

Indications For Use: to provide padding for patient comfort during x-ray visualization of the breast.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR Over-The-Counter Use** _____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003795